

Docket No.: 13907-00007-US  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

---

In re Patent Application of:  
Ulrich Hersel et al.

Application No.: 10/594,097

Confirmation No.: N/A

Filed: September 25, 2006

Art Unit: N/A

For: POLYMERIC PRODRUG WITH A SELF-  
IMMOLATIVE LINKER

---

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this

Application No.: 10/594,097

Docket No.: 13907-00007-US

application by this firm) to our Deposit Account No. 03-2775, under Order No. 13907-00007-US.

Dated: March 6, 2007

Respectfully submitted,

By 

Aaron R. Ettelman

Registration No.: 42,516

CONNOLLY BOVE LODGE & HUTZ LLP

1007 North Orange Street

P.O. Box 2207

Wilmington, Delaware 19899

(302) 658-9141

(302) 658-5614 (Fax)

Attorney for Applicant

Application No. (if known): 10/594,097

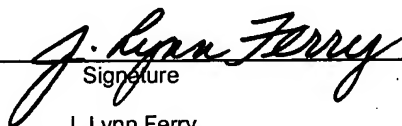
Attorney Docket No.: 13907-00007-US

## Certificate of Mailing under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

MS PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on March 6, 2007  
Date



Signature

J. Lynn Ferry

Typed or printed name of person signing Certificate

Registration Number, if applicable

(302) 658-9141

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Information Disclosure Statement (2 pages)  
IDS (Citation) by Applicant (33 References) (2 pages)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete If Known</b>	
				Application Number	10/594,097
				Filing Date	September 25, 2006
				First Named Inventor	Ulrich Hersel
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	13907-00007-US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-6,720,306-A1	04-13-2004	Greenwald et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number- Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
	BA	WO-99/30727	06-24-1999	Enzon Inc et al.		See US-6720306
	BB	WO-02/089789	11-14-2002	Enzon Inc		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T <sup>2</sup>
	CA	NA et al., "Monitoring of peptide acylation inside degrading PLGA microspheres by capillary electrophoresis and MALDI-TOF mass spectrometry," <i>Journal of Controlled Release</i> , (2003), pp. 291-299, Vol. 92.				
	CB	DUNCAN, "The Dawning Era of Polymer Therapeutics," <i>Nature Reviews</i> , (May 2003), pp. 347-360, Vol. 2.				
	CC	MATSUMURA et al., "A New Concept for Macromolecular Therapeutics in Cancer Chemotherapy: Mechanism of Tumor-tropic Accumulation of Proteins and the Antitumor Agent Smancs," <i>Cancer Research</i> , (December 1986), pp. 6387-6392, Vol. 46.				
	CD	CALICETI et al., "Pharmacokinetic and biodistribution properties of poly(ethylene glycol)-protein conjugates," <i>Advanced Drug Delivery Reviews</i> , (2003), pp. 1261-1277, Vol. 55.				
	CE	PELEG-SCHULMAN et al., "Reversible PEGylation: A Novel Technology to Release Native Interferon $\alpha 2$ over a Prolonged Time Period," <i>J. Med. Chem.</i> , (2004), pp. 4897-4904, Vol. 47.				
	CF	TESTA et al., "Metabolic Hydrolysis and Prodrug Design," <i>Hydrolysis in Drug and Prodrug Metabolism</i> , (2003), pp. 4-5.				
	CG	LUO et al., "A Hyaluronic Acid-Taxol Antitumor Bioconjugate Targeted to Cancer Cells," <i>Biomacromolecules</i> , (2000), pp. 208-218, Vol. 1.				
	CH	CHENG et al., "Synthesis of Linear, $\beta$ -Cyclodextrin-Based Polymers and Their Camptothecin Conjugates," <i>Bioconjugate Chem.</i> , (2003), pp. 1007-1017, Vol. 14.				
	CI	BHATT et al., "Synthesis and in Vivo Antitumor Activity of Poly(L-glutamic acid) Conjugates of 20(S)-Camptothecin," <i>J. Med. Chem.</i> , (2003), pp. 190-193, Vol. 46.				
	CJ	GREENWALD et al., "Drug Delivery Systems Employing 1,4- or 1,6-Elimination: Poly(ethylene glycol) Prodrugs of Amine-Containing Compounds," <i>J. Med. Chem.</i> , (1999), pp. 3657-3667, Vol. 42.				
	CK	TESTA et al., "The Hydrolysis of Carboxylic Acid Ester Prodrugs," <i>Hydrolysis in Drug and Prodrug Metabolism</i> , (2003), pp. 420-534, Chapter 8.				

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete If Known</b>	
				Application Number	10/594,097
				Filing Date	September 25, 2006
				First Named Inventor	Ulrich Hersel
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	13907-00007-US

CL	CAVALLARO <i>et al.</i> , "Polymeric Prodrug for Release of an Antitumoral Agent by Specific Enzymes," <i>Bioconjugate Chem.</i> , (2001), pp. 143-151, Vol. 12.
CM	SATCHI-FAINARO <i>et al.</i> , "PDEPT: Polymer-Directed Enzyme Prodrug Therapy. 2. HPMA Copolymer- $\beta$ -lactamase and HPMA Copolymer-C-Dox as a Model Combination", <i>Bioconjugate Chem.</i> , (2003), pp. 797-804, Vol. 14.
CN	DUNCAN <i>et al.</i> , "Polymer-drug conjugates, PDEPT and PELT; basic principles for design and transfer from the laboratory to clinic," <i>Journal of Controlled Release</i> , (2001), pp. 135-146, Vol. 74.
CO	WIWATTANAPATAPEE <i>et al.</i> , "Dendrimers conjugates for colonic delivery of 5-aminosalicylic acid," <i>Journal of Controlled Release</i> , (2003), pp. 1-9, Vol. 88.
CP	GARMAN <i>et al.</i> , "The preparation and properties of novel reversible polymer-protein conjugates," <i>FEBS Letters</i> , (November 1987), pp. 361-365, Vol. 223, No. 2.
CQ	LEE <i>et al.</i> , "Drug Delivery Systems Employing 1,6-Elimination: Releasable Poly(ethylene glycol) Conjugates of Proteins," <i>Bioconjugate Chem.</i> , (2001), pp. 163-169, Vol. 12.
CR	GREENWALD <i>et al.</i> , "Drug Delivery Systems Based on Trimethyl Lock Lactonization: Poly(ethylene glycol) Prodrugs of Amino-Containing Compounds," <i>J. Med. Chem.</i> , (2000), pp. 475-487, Vol. 43.
CS	GREENWALD <i>et al.</i> , "A New Aliphatic Amino Prodrug System for the Delivery of Small Molecules and Proteins Utilizing Novel PEG Derivatives," <i>J. Med. Chem.</i> , (2004), pp. 726-734, Vol. 47.
CT	SHABAT <i>et al.</i> , "Chemical Adaptor Systems," <i>Chem. Eur. J.</i> , (2004), pp. 2626-2634, Vol. 10.
CU	LEE <i>et al.</i> , "Targeted Enzyme-Responsive Drug Carriers: Studies on the Delivery of a Combination of Drugs," <i>Angew. Chem.</i> , (2004), pp. 1707-1710, Vol. 116.
CV	PEPPAS <i>et al.</i> , "Hydrogels in pharmaceutical formulations," <i>European Journal of Pharmaceutics and Biopharmaceutics</i> , (2000), pp. 27-46, Vol. 50.
CW	HENNINK <i>et al.</i> , "Novel crosslinking methods to design hydrogels," <i>Advanced Drug Delivery Reviews</i> , (2002), pp. 13-36, Vol. 54.
CX	ESFAND <i>et al.</i> , "Poly(amidoamine) (PAMAM) dendrimers: from biomimicry to drug delivery and biomedical applications," <i>DDT</i> , (April 2001), pp. 427-436, Vol. 6, No. 8.
CY	BOAS <i>et al.</i> , "Dendrimers in drug research," <i>Chem. Soc. Rev.</i> , (2004), pp. 43-63, Vol. 33.
CZ	GRAYSON <i>et al.</i> , "Convergent Dendrons and Dendrimers: from Synthesis to Applications," <i>Chem. Rev.</i> , (2001), pp. 3819-3867, Vol. 101.
CA1	GREENE <i>et al.</i> , "Protective Groups in Organic Synthesis," <i>John Wiley &amp; Sons</i> , (1999), Third Edition.
CB1	AMIR <i>et al.</i> , "Self-Immolative Dendrimers," <i>Angew. Chem. Int. Ed.</i> , (2003), pp. 4494-4499, Vol. 42.
CC1	SAUERBREI <i>et al.</i> , "An Enzyme-Labile Linker Group for Organic Syntheses on Solid Supports," <i>Angew. Chem. Int. Ed.</i> , (1998), pp. 1143-1146, Vol. 37, No. 8.
CD1	DE GROOT <i>et al.</i> , "Elongated Multiple Electronic Cascade and Cyclization Spacer Systems in Activatable Anticancer Prodrugs for Enhanced Drug Release," <i>J. Org. Chem.</i> , (2001), pp. 8815-8830, Vol. 66.
CE1	ANTCZAK <i>et al.</i> , "A New Acivicin Prodrug Designed for Tumor-Targeted Delivery," <i>Bioorganic &amp; Medicinal Chemistry</i> , (2001), pp. 2843-2848, Vol. 9.

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	Date Considered
--------------------	-----------------